

PRIVACY: Do federal or state laws, or your institution’s privacy or confidentiality policies, restrict disclosure (research or IRB policies are addressed under “ethics” below)?

Does the data to be shared include identifiable health information?

Deidentified Data Sets

A deidentified data set (“DDS”) – one that omits all direct and indirect identifiers – may be shared with researchers without restriction, as long as other considerations (proprietary, contractual, ethical) do not otherwise limit disclosure. To be considered de-identified, the data set must exclude the following elements with respect to an individual or the individual’s relatives, employers, or household members:

- Name
- Address, city, and other geographic information smaller than state (3-digit zip code may be included only for an area where more than 20,000 people live)
- All elements of date (except year), plus age and any date, including year, if age is over 89 (date or age ranges may be included)
- Telephone, fax, e-mail, web URL, IP address
- Social security number, medical record number, health plan beneficiary number, account number, certificate or license number
- Vehicle identifier (e.g., license plate or serial number)
- Device identifier (e.g., serial number)
- Biometric identifier (e.g., finger print or voice print – DNA is *not* considered a direct or indirect identifier under HIPAA)
- Full-face photograph or comparable image
- Any other unique identifying number, characteristic, or code.

Most institutions will agree that de-identified data sets may be shared with few or no constraints and, therefore, can be exchanged in the “green lane,” with researchers who have agreed to the general terms of use of caBIG™ applications and data.

Does the data to be shared include identifiable health information?

Limited Data Sets

A limited data set (“LDS”) is similar to a de-identified data set but may include geographic information other than street address; dates and ages; and other unique identifying numbers, characteristics, or codes. An LDS may be shared with researchers who sign a *data use agreement* to assure that they will use the data only for the designated research, will protect the data against inappropriate disclosure, and will not use the information to re-identify the included individuals.

HIPAA prescribes very specifically the requirements for a data use agreement. An agreement that meets HIPAA’s standards is under development by DSIC.

Does the data to be shared include identifiable health information?

Identifiable Data Sets

HIPAA generally permits an identifiable data set to be shared only with the specific written agreement (“authorization”) of the individuals whose data will be disclosed, or under a waiver of authorization approved by an IRB or privacy board. Preliminary data reviews “preparatory to research,” and research involving information of only deceased subjects are also permitted.*

Most institutions will share identifiable data only under agreements that assure confidential treatment of the data to be exchanged. These agreements may be simple or more complex, depending on other considerations.

DSIC is in the process of developing an agreement that assures confidentiality protections for identifiable data to be exchanged via caGrid we believe will be acceptable to most institutions.

Do state laws further restrict disclosure?

Some states have enacted laws considered to be “more restrictive” than HIPAA, typically to provide additional protection to particularly “sensitive” data. Examples of these laws are laws restricting use and disclosure of genetic testing information, cancer diagnosis information, HIV/AIDS and other serious communicable disease information, and information about substance abuse or mental health treatment. Many of these laws include exceptions for research uses of the data or for data sets that have been de-identified. Some may require contracts supporting exchange of sensitive data to include certain language. If the caGrid standard terms of use available in the green, yellow or orange lanes do not address your needs, please contact DSIC for assistance: [BAH?]

Do institutional policies further restrict disclosure?

Research institutions rarely restrict data exchange beyond the requirements of federal or state law for privacy reasons (analysis of other elements of the framework is included in the other sections of this document). If your institution does impose such restrictions, however, please contact DSIC for assistance: [BAH?] [SHOULD WE MENTION THAT ADOPTERS HAVE ALREADY AGREED? IF SO, I'D INCLUDE THE ACTUAL LANGUAGE]

* Projects undertaken primarily for disease management or quality improvement purposes but that also include a research component do not require waiver or authorization under HIPAA, though they often require IRB oversight and consent or waiver of consent under the Common Rule, 45 CFR part 46.